



**STATE BOARD OF EQUALIZATION  
STAFF LEGISLATIVE ANALYSIS**

DRAFT

Date Introduced:	<b>02/25/09</b>	Bill No:	<b><u>SB 341</u></b>
Tax:	<b>Drug Manufacturer Fee</b>	Author:	<b>DeSaulnier</b>
Related Bills:			

***This analysis will only address the bill's provisions that impact the Board.***

**BILL SUMMARY**

This bill would require the Board of Equalization (Board) to annually assess and collect a fee on manufacturers of drugs sold in the state.

**ANALYSIS**

**CURRENT LAW**

Under existing law, a state and local sales and use tax is imposed on the sale or use of tangible personal property in this state, including prescription drugs, unless specifically exempted in the law. Section 6369, for example, provides an exemption for prescription medicines sold or furnished under specified conditions.

The total combined sales and use tax rate, effective April 1, 2009<sup>1</sup>, is between 8.25 and 10.25 percent, depending on the location in which the merchandise is sold. The Board does not collect any additional taxes or fees on the prescription drugs.

**PROPOSED LAW**

This bill would add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 to the Health and Safety Code to enact the Drug Safety and Effectiveness Program (Program).

Among other things, this bill would require the California Department of Public Health (CDPH) to make every effort to enter into a contract or agreement with the University of California to establish a program to evaluate scientific literature it determines relevant to the safety and effectiveness of prescription drugs in the state that would have the following components:

- A determination of the classes of prescription drugs that are advertised to consumers, marketed to physicians, or both, in the state.
- An Internet Web site that would report information on the safety and effectiveness of brand name and generic drugs in the classes, as identified, including, when available, direct comparisons of relative safety and effectiveness, and differential safety and effectiveness of specific drugs according to age, gender, race, or ethnicity.

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<sup>1</sup> Effective April 1, 2009, AB X3 3 (Chapter 18 of the Third Extraordinary Session, signed by Governor Schwarzenegger on February 20, 2009) temporarily increases the state sales and use tax rate by 1 percent. The 1 percent tax rate increase will expire on either July 1, 2011, or July 1, 2012, depending upon whether California voters approve the proposed Budget Stabilization constitutional amendment in a statewide election to be held on May 19, 2009.

***This staff analysis is provided to address various administrative, cost, revenue and policy issues; it is not to be construed to reflect or suggest the Board's formal position.***

This bill would also impose a fee on manufacturers of drugs sold in the state. The amount of the fee would be determined by the CDPH, in consultation with the University of California, and would be limited to the amount necessary to fund the actual and necessary expenses of the university, the CDPH, and the Board in implementing the Program. The total annual assessment on drug manufacturers would not exceed three million five hundred thousand dollars (\$3,500,000).

The drug manufacturer fee would be established by the CDPH, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of drugs sold in the state, based on the total dispensed retail dollar amount in the year prior to the assessment. A fee would not be assessed on a drug manufacturer that could demonstrate, as determined by the CDPH, that it does not manufacture drugs that are advertised to consumers or marketed to physicians in the state.

The fee would be assessed and collected annually by the Board in accordance with the Fee Collection Procedures Law (Part 20 (commencing with Section 55001) of Division 2 of the Revenue and Taxation Code). The Board would be authorized to prescribe, adopt, and enforce regulations, including, but not limited to, provisions governing collections, reporting, refunds, and appeals.

The CDPH would provide to the Board the name and address of each person or entity that is liable for a fee or expense, the amount of the fee, and date the fee is due.

The CDPH would handle appeals or claims for refund if the petition or claim is founded upon the grounds that the CDPH has improperly or erroneously calculated the amount of the fee or has incorrectly determined that the person is subject to the fee.

The fees collected would be deposited into the Drug Safety and Effectiveness Program Fund (Fund), which this bill would establish in the State Treasury. Moneys in the Fund would be expended, upon appropriation by the Legislature, for the purposes of the Program, including the payment of refunds of the fee and reimbursement to the Board for its administrative costs. All interest earned on the moneys deposited into the Fund would be retained in the Fund.

The provisions imposing a fee on manufacturers of drugs sold in this state would not be implemented until the CDPH and the University of California enter into a contract or agreement, as specified. The CDPH would be required to notify the Board when this contract or agreement has been entered into, and the Board would not be required to collect the first payment of the fee until seven and one-half months after the date of the contract or agreement.

#### BACKGROUND

This bill is virtually identical to AB 71 (Chan and Frommer), which was introduced in the 2005-06 Legislative Session, but failed passage on the Senate Floor.

#### COMMENTS

1. **Sponsor and purpose.** This bill is sponsored by the California Alliance of Retired Americans and is intended to provide consumers more information on the safety and effectiveness of prescription drugs they are taking and thereby encourage them to discuss such information with their physicians.

2. **Could the state require out-of-state retailers to remit a drug fee?** Various Supreme Court cases have focused on states' ability to impose the use tax on out-of-state firms making sales to in-state customers. In 1967 the Supreme Court ruled in *National Bellas Hess, Inc. v. Illinois Department of Revenue* (1967) 386 U.S. 753, that a firm that has no link to a state except mailing catalogs to state residents and filling their orders by mail cannot be subject to that state's sales or use tax. The Court ruled that these mail order firms lacked substantial physical presence, or nexus, required by the Due Process Clause and the Commerce Clause of the United States Constitution.

In the 1977 case of *Complete Auto Transit, Inc. v. Brady* (1977) 430 U.S. 274 the Court articulated that, in order to survive a Commerce Clause challenge, a tax must satisfy a four part test: 1) it must be applied to an activity with a substantial nexus with the taxing State, 2) it must be fairly apportioned, 3) it does not discriminate against interstate commerce, and 4) it must be fairly related to the services provided by the State.

North Dakota enacted anti-National Bellas Hess legislation with the expressed purpose of creating nexus with mail order firms selling to consumers in the state, in an attempt to compel out-of-state retailers to collect the use tax on mail order sales and test the continuing validity of the National Bellas Hess decision. The statute was challenged, and in 1992 the Supreme Court issued a ruling in *Quill Corporation v. North Dakota* (1992) 504 U.S. 298. The Court in *Quill* applied the *Complete Auto Transit* analysis and held that satisfying due process concerns does not require a physical presence, but rather requires only minimum contacts with the taxing state. Thus when a mail-order business purposefully directs its activities at residents of the taxing state, the Due Process Clause does not prohibit the state's requiring the retailer to collect the state's use tax. However, the Court held further that physical presence in the state was required for a business to have a "substantial nexus" with the taxing state for purposes of the Commerce Clause. The Court therefore affirmed that in order to survive a Commerce Clause challenge, a retailer must have a physical presence in the taxing state before that state can require the retailer to collect its use tax.

Based on the above cases, it is questionable whether the state could require an out-of-state manufacturer of drugs, who has no physical presence in California, to remit a fee.

3. **How would the Board be funded for administrative start-up costs?** This bill proposes a fee paid by drug manufacturers. In order to implement the fee collection provisions, it is necessary that the Board develop computer programs, answer feepayer inquiries, mail determinations, process payments, and develop forms and publications. These functions would occur before fees are collected and deposited into the new Fund. Typically, the Board would seek payment from the Fund for administrative start-up costs through the budget change proposal process. However, the Fund would not have a balance to reimburse the Board's administrative start-up costs prior to the collection of the fee. To address this funding issue, this bill should be amended to add language authorizing a loan from the General Fund to the Fund if the CDPH enters into a contract or agreement with the University of California with repayment from fees collected and deposited into the fund.

4. **Legal challenges of any new fee program might be made on the grounds that the fee is a tax.** In July 1997, the California Supreme Court held in *Sinclair Paint Company v. State Board of Equalization* (1997) 15 Cal.4th 866 that the Childhood Lead Poisoning Prevention Act of 1991 imposed bona fide regulatory fees and not taxes requiring a two-thirds vote of the Legislature under Proposition 13. In summary, the Court found that while the Act did not directly regulate by conferring a specific benefit on, or granting a privilege to, those who pay the fee, it nevertheless imposed regulatory fees under the police power by requiring manufacturers and others whose products have exposed children to lead contamination to bear a fair share of the cost of mitigating those products' adverse health effects.

Although this measure has been keyed by the Legislative Counsel as a majority vote bill, opponents of this measure might question whether the fees imposed are in legal effect "taxes" required to be enacted by a two-thirds vote of the Legislature.

5. **Administrative and technical amendments.** The bill has several administrative issues that would need to be addressed before the bill becomes law.

Some of the administrative issues are:

- Subdivision (f) provides that the bill's provisions shall not be implemented until the CDPH and the University of California (University) enter into a contract or agreement; and, provides that the Board may delay the first collection of the fee until seven and one-half (7½) months from the date of the CDPH and the University contract agreement. The Board could not begin implementation until the date of the CDPH and University contract agreement. Subdivision (f) requires that the CDPH notify the Board when the contract agreement has been entered into; however, there is no time deadline for the CDPH to provide such notice. The Board would need the entire seven and one-half (7½) months period to implement the bill's provisions. If CDPH takes 30 days from the date the contract is entered into to notify the Board, the Board will have lost one-month implementation time. For this reason, staff recommends amending the bill to specify that the seven and one-half (7½) months lead-time starts upon the Board receiving notice from the CDPH.
- Subdivision (c)(2) requires the CDPH to provide to the Board the name and address of each person or entity that is liable for a fee or expense and the amount of the fee. However, the bill does not specify a due date when the CDPH is to provide this information. The bill should provide an adequate lead-time for the Board to send the feepayers an assessment for the amount specified by the CDPH.
- Subdivision (c)(1) provides that the Board shall collect the fee in accordance with the Fee Collections Procedure Law. The Fee Collections Procedures Law contains "generic" administrative provisions for the administration and collection of fee programs administered by the Board. Among other things, it includes collection, reporting, refund and appeals provisions. However, it does not include specific due dates for each fee. For this reason, it is suggested that this bill provide a due date for the drug manufacturer fee.
- Subdivision (c)(1) makes an incorrect reference to the Fee Collection Procedures Law. The Fee Collections Procedures Law is in *Part 30*, not *Part 20*, (commencing with Section 55001) of Division 2 of the Revenue and Taxation Code.

Staff will work with the author's office to address the various issues as the bill progresses through the legislative process.

**COST ESTIMATE**

The Board would incur non-absorbable costs to adequately develop and administer a new fee program. These costs would include notifying feepayers, developing forms and publications, writing computer programs, mailing and processing determinations and payments, training staff, and answering feepayer inquiries. A cost estimate of this workload is pending.

**REVENUE ESTIMATE**

This measure does not specify the amount of the proposed fee. Accordingly, a revenue estimate could not be prepared.

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